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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,636	03/24/2004	Jun Feng	DPP-IV-5004-CI	7481
32793 7590 01/31/2007 TAKEDA SAN DIEGO, INC. 10410 SCIENCE CENTER DRIVE SAN DIEGO, CA 92121			EXAMINER HABTE, KAHSA Y	
			ART UNIT	PAPER NUMBER
			1624	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/31/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/809,636

Applicant(s)

FENG ET AL.

Examiner

Kahsay Habte

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-15,19-21,23,26-31,33 and 36-62 is/are pending in the application.
- 4a) Of the above claim(s) 37-41,44-54 and 62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-15,19-21,23,26-31,33,36,42,43 and 55-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/23/07, 11/15/06 & 9/26/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1, 3-15, 19-21, 23, 26-31, 33 and 36-62 are pending in this application.

Response to Amendment

2. Applicant's amendment filed 1/3/2007 in response to the previous Office Action (9/1/2007) is acknowledged. Rejections of claims 1-33, 36, 42-43, 55-61, 87-88, 95, 99-100 and 103 under 35 U.S.C. § 112, second paragraph (items 6b and 6d-6e) and the double patenting rejection (items 7-8) have been maintained. The prior art rejection (item 5) and the second paragraph rejection (items 6a and 6c) have been obviated.

Election/Restriction

3. Applicant's election of a single species: 2-[2-(3-Amino-piperidin-1-yl)-6-fluoro-4-oxo-4H-quinazolin-3-ylmethyl]-benzonitrile (Example 6 disclosed at page 115 of the specification) filed 4/13/2006 is acknowledged. Applicants have elected a quinazoline species and the examiner searched the invention by expanding the variables around the elected species. The search was stopped when the examiner found a prior art. As it was discussed with Mr. David Weitz on 4/27/2006, the nature of the invention is very broad (see for example restriction requirement of a related case 10/809,637). It was recommended that applicants define the variables R_1 and R_2 as discussed during the telephonic interview (4/27/2006) and also define variables R_3 and R_4 as " R_3 and R_4 together form a benzo ring". Since the elected invention is drawn to quinazoline, other

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definitions of variables R_3 and R_4 that would result in different core structure should be deleted.

Claims 37-41, 44-54 and 62 are drawn to non-quinazolines, stand withdrawn from further consideration as not being readable on the elected species.

Information Disclosure Statement

4. Applicant's Information Disclosure Statement, filed on 1/23/2007, 11/15/2006 and 9/26/2006 has been acknowledged. Please refer to Applicant's copies of the 1449 submitted herewith.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-15, 19-21, 23, 26-31, 33 and 36, 42-43 and 55-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. In claim 1 or elsewhere in the claims, the phrase "U is a moiety providing 3 atom separation between V and the ring to which R_2 is attached" is indefinite. What is covered by U and what is not? It is recommended that applicants recite specific linkers for U to overcome this rejection.

Response to arguments

Applicant's argument filed 01/03/2007 has been fully considered but it is not persuasive.

Applicants argue that they have amended claims 1 and 42 to recite "U provides a 3 atom separation between V and the ring to which R₂ is attached", but this amendment would not overcome the rejection. What is covered and what is not by the 3 atoms separation? Applicants are silent in responding to the simple question raised in the previous Office Action? What is the complete list of linkers? Note that the definition of R₂ remains vague and indefinite.

Note that claims 7 and 11 recite carbocyclic and heterocyclic rings for UV, but there is no linker (3 atoms) between V and said rings. The rings are directly attached to the quinazoline ring. Where are the three atom linkers?

b. In claim 1 or elsewhere in the claim, the phrase "V comprises a basic nitrogen atom that is capable of interacting with a carboxylic acid side chain of an active site residue of a protein" is not clear. Is the ring nitrogen capable of interacting with carboxylic acid or the substituent on the ring is capable of interacting with carboxylic acid? The term "comprises" is also an open-ended language.

Response to arguments

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Applicant's argument filed 01/03/2006 has been fully considered but it is not persuasive.

Applicants argue, "Claims 1 and 42 are being amended to recite that V comprise a primary, secondary or tertiary amine, a heterocycloalkyl comprising a nitrogen ring atom,....". The examiner disagrees with applicant's argument. First of all, the terms "comprising" or "comprise" are an open-ended language. The claims with said terms remain indefinite, since one skilled in the art would not know if other substituents, atoms, compounds, composition etc. are included or not. The phrase "V comprisesa basic nitrogen atom" remains indefinite since it is unclear what other atoms or compounds are present beside the basic nitrogen atom. It is recommended that applicants define specific rings of V as it is done in claim 7.

In regard to the functional language "that is capable of interacting with a carboxylic acid side chain of an active site residue of a protein", it is recommended that applicants delete said language.

c. In claim 1, the phrase "R₃ and R₄ are taken together to form 6-membered ring" is indefinite. What is the nature of the ring? What is covered and what is not? It is recommended that applicants amend the claim as "R₃ and R₄ are taken together to form...a benzo ring".

Response to arguments

Applicant's argument filed 01/03/2007 has been fully considered but it is not persuasive.

Applicants argue, "that one of ordinary skill in the art would understand the bounds of the phrase as it is used in the present claims. However, for sole purpose of advancing prosecution of the present application, Applicants are amending claim 1 to recite6-memberd ring". The examiner disagrees with applicants. It is true applicants deleted limited the size of the ring from 5-6-membered to 6-memberd ring, but they did not overcome the second paragraph rejection. Applicants are silent to answer simple questions raised in previous Office Action. What is covered by ring what is not? Is a polymer compound with a ring included or not? Is it heterocyclic ring? Is it heteroaryl ring? Bicyclic ring? Tricyclic ring? Polycyclic? Aromatic ring? Fused ring? Spiro ring? Note that "ring" literally covers any compound with a cyclic nature that 6-membered. Since the elected species are drawn to quinazolines, it is required that applicants amend the claim as "R₃ and R₄ are taken together to form a benzo ring". Note that a "ring" without heteroatom or nature of the ring is indefinite.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

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from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1, 3-15, 19-21, 23, 26-31, 33, 36, 42-43 and 55-61 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 8-9, 11-17, 19, 23, 26-27, 29, 37-39, 51-57, 83-84, 95, 99 and 111 of copending Application No. 10/809,635. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is

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significant overlap between the instant claims and claims 1-5, 8-9, 11-17, 19, 23, 26-27, 29, 37-39, 51-57, 83-84, 95, 99 and 111 of copending Application No. 10/809,635.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to arguments

Applicant's argument filed 01/03/2007 has been fully considered but it is not persuasive.

Applicants indicate that they intend to address the rejection when one or both of the applications are otherwise in condition for allowance.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

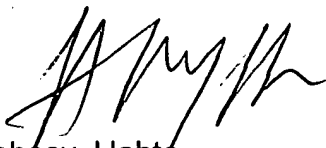
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte whose telephone number is (571)-272-0667. The examiner can normally be reached on M-F (9.00- 5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kahsay Habte
Primary Examiner
Art Unit 1624

January 24, 2007